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#### **VIA ELECTRONIC FILING**

Magistrate Judge Nathanael Cousins **United States District Court** Courtroom A – 15<sup>th</sup> Floor 450 Golden Gate Avenue San Francisco, CA 94102

> Re: Allen et al., v. ConAgra Foods, Inc., No. 3:13-cv-01279-JST Plaintiff's Supplemental Discovery Letter Brief Re PAM® Relevance

Dear Magistrate Judge Cousins:

Counsel for Plaintiff Erin Allen hereby submits this Supplemental Letter Brief explaining the relevancy of PAM® discovery that Plaintiff seeks in letter briefs 78 and 79.

#### I. **SUMMARY**

ConAgra contends that Spray Butter (namely Parkay Spray®) belongs in the FDA's "Nonstick Cooking Spray" reference category. The FDA has given little guidance as to what qualifies a product as belonging in that category, other than to list a single prime example – PAM®. To be sure, the Cooking Spray category developed entirely around PAM®. Whether other products, such as Parkay Spray®, belong in that category depends on "customary usage" – namely whether those products have similar product characteristics, dietary usage and customarily consumed amounts as "Nonstick Cooking Sprays (e.g., PAM®)."<sup>2</sup>

ConAgra does not dispute that the customary usage of its Spray Butter is at-issue. But the question remains whether Spray Butter's customary usage places it in a category the FDA has defined for "nonstick cooking sprays" with reference to PAM®. Well, what is the customary usage of PAM®? That is the question to which Plaintiff seeks an answer.

ConAgra is in a unique position regarding the customary usage of PAM® – it owns the product. In fact, the regulatory history suggests that in 1991 ConAgra petitioned the FDA to create the Cooking Spray category for PAM®. So not only does it possess customary usage

<sup>2</sup> 21 C.F.R. 101.12(a)(9)

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data, it possesses data and arguments to and from the FDA leading to the creation of the very product category they now seek to hide behind to dodge liability.

ConAgra has not shown (or even tried to show) that discovery relating to PAM® is unduly burdensome.<sup>3</sup> In fact, it has indicated that few FDA communications and market research studies even exist. Instead, ConAgra misconstrues Plaintiff's requests as facially overbroad. To be clear, Plaintiff is not requesting communications from every governmental agency – only the FDA. Nor do her PAM®-related discovery requests span 15+ years. For example, Plaintiff seeks communications with the FDA relating to discrete events that likely occurred over several months. Surely ConAgra can readily access these important government communications and expensive market research studies.

If ConAgra were to withdraw its argument that Parkay Spray® belongs in the same FDA reference category as PAM®, then the customary usage for those products would no longer be relevant. But by pursuing this line of defense, it has placed this information directly at-issue.

#### II. DETAILED ARGUMENT

# A. PAM's® Labeling, Nature and Nutrition Information, and Market Research are Relevant to Whether Parkay Spray® is a "Nonstick Cooking Spray (e.g., PAM®)."

ConAgra sells a "Parkay" product (Parkay Spray®) that declares on its label "fat free," "0 fat" and "0 calories"—claims which ConAgra does not dispute are literally untrue (indeed, a bottle of Parkay Spray® is laden with fat and calories). Nonetheless, ConAgra tries to justify these claims by arguing that -- under FDA regulations -- Parkay Spray® may be classified as a "nonstick cooking spray (e.g., PAM®)" with a required serving size of only 0.25 grams. By misclassifying Parkay Spray® with PAM® (treating both as nonstick cooking sprays), ConAgra constructs an argument that Parkay Spray® contains less than 5 calories and less than 0.5 g of fat per serving, which ConAgra rounds down to zero under the regulations.

Plaintiff disagrees. She asserts that Parkay Spray® is primarily used as a food topping, not as a lubricant for cookware and should be classified as a butter alternative with a required serving size of 1 tablespoon. Critically, if Plaintiff is correct, ConAgra cannot lawfully claim that Parkay Spray® is fat-free or calorie-free.<sup>4</sup>

Plaintiff intends to show that Parkay Spray® should not be classified as a "nonstick cooking spray (e.g., PAM®)". This entails an analysis of:

<sup>&</sup>lt;sup>3</sup> Big Baboon Corp. v. Dell, Inc., 723 F. Supp. 2d 1224, 1229 (C.D. Cal. 2010) (party resisting discovery must substantiate undue burden objections).

<sup>&</sup>lt;sup>4</sup> Given this, the district court previously found that "the question posed by this consumer fraud action" is whether Parkay Spray® is more like PAM® or liquid butter. ECF 41, at p. 1.

- How ConAgra promotes these two products differently (PAM® for lubricating cookware and Parkay Spray® for a buttery food topping). (i.e., <u>labeling</u>)
- PAM's® product attributes as distinguished from Parkay Spray®, i.e., what makes PAM® a nonstick cooking spray and how does that differ from Parkay Spray®? (i.e., nature and nutrition content)
- The nonstick cooking spray market, which developed around PAM® exclusively. Why is Parkay Spray® analyzed in ConAgra's market research as being in a different market segment than PAM®? (i.e., market research)

#### Topic 7: (Labeling of PAM®)

ConAgra acknowledges that PAM® labeling is relevant to serving size issues and has agreed: (i) to produce sample labels (2009-present); and (ii) to designate a witness to provide testimony about serving sizes listed on PAM® products during the class period. The labeling documents and the time period for this topic are not in dispute.

The pertinent inquiry, however, concerns the labeling and marketing of PAM® *as a no-stick cooking spray*. ConAgra's testimony on this matter is even more important than testimony about the labeled serving size. Indeed, the labeled serving size is simply based on Pam being a *no-stick cooking spray* in the first place.

Consider how ConAgra labels PAM®: there is a picture of a glistening pan, a description "Superior No-Stick Results," a statement "NO-STICK COOKING SPRAY," a representation that the product is "specially formulated to provide the ultimate no-stick performance," and of course the primary ingredient—oil. Plaintiff can and will show how ConAgra labels and markets PAM® differently than Parkay Spray®. PAM® is marketed and labeled for no-stick performance, Parkay Spray® as a buttery food topping.

Thus, testimony about the labeling of PAM® as a no-stick cooking spray bears on ConAgra's classification of Parkay Spray® in the same reference category as PAM®.

### Topic 9: (Nature/Nutrition Content of PAM®)

Plaintiff needs to ask about PAM's® nature and nutrition content to define the salient features of a nonstick cooking spray. This will demonstrate why Parkay Spray® is not a nonstick cooking spray. For example, the high percentage of oil—indeed the primary ingredient of PAM®—reflects PAM's® utility as a lubricant for cookware. Plaintiff will show that Parkay Spray® does not share these salient features.

#### RFP No. 3: (Market Research for PAM®)

ConAgra has already produced *some* market research for PAM®. It cannot, however, cherry-pick those documents, which are less disruptive to its claims<sup>5</sup> and withhold more damaging ones on the basis of relevancy. If ConAgra is allowed to argue that Parkay Spray® is a "nonstick cooking spray (e.g., PAM®)", it should produce all documents addressing this issue, not simply those of its choosing.

In August 2011, a Senior Director of Consumer Insights for Parkay Spray® helped to put together one study that covered Parkay Spray®—in the process, she looked into a separate PAM® study. This Senior Director is one of ConAgra's 30(b)(6) designees and an individual deponent. Plaintiff does not believe that ConAgra has produced this PAM® study which plainly bears on issues in this case and is likely to lead to the discovery of admissible evidence.

Defendant offers no evidence that the request for market research is unduly burdensome and proposes no means to reduce any purported burden. If, however, the Court concludes that Plaintiff's request is still too burdensome, Plaintiff asks the Court to compel production of the aforementioned PAM® study.

## B. FDA Communications About PAM® are Relevant to Whether Parkay Spray® is a "Nonstick Cooking Spray (e.g., PAM®)"

An historical note is in order. In 1990, there was a serving size sub-category for "butter, margarine, oil, lard, shortening" (1 tablespoon)...but there was no "spray types" sub-category.<sup>6</sup> In 1991, after meeting with industry groups, the FDA created a "spray type" sub-category for "nonstick cooking sprays (e.g., PAM®)." <sup>7</sup> Because consumers do not consume nonstick cooking sprays in the same manner that they consume food toppings, the new spray-types sub-category warranted a .25g serving size. Years later, butter spray-pump food toppings (i.e., Spray Butters) were introduced, including Parkay Spray®.

### RFP No. 4 / Topic 10: (Regulatory Communications about PAM®)

Is Parkay Spray® a "nonstick cooking spray (e.g., PAM®)" *according to the FDA*? Unfortunately, the FDA never got the chance to weigh-in. Spray Butters were not on the market in 1991. Communications about PAM® leading to the formation of this product category are,

<sup>&</sup>lt;sup>5</sup> The limited market research that ConAgra produced to date still reflects how PAM® is designed for no-stick cooking (and is thus relevant).

<sup>&</sup>lt;sup>6</sup> Food Labeling; Serving Sizes, 55 F.R. 29517-01 (July 19, 1990).

<sup>&</sup>lt;sup>7</sup> Food Labeling Serving Sizes, 56 F.R. 60394-01 (November 27, 1991); The FDA Guidance explicitly defines the "spray types" fats and oils sub-category as "nonstick cooking sprays (e.g., Pam)." Product Categories and Products, FDA Inspection Guides, available at http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm114704.htm

however, highly relevant. So too are communications reflecting PAM's® essential product characteristics, dietary uses and customary consumption amounts. These communications will sculpt and define the "spray types" category. They answer two important questions: (1) "What did ConAgra tell the FDA about PAM® to warrant a new reference category?" And (2) "What does the FDA think about this type of product?"

Communications leading to formation of the "spray types" category are relevant no matter when they occurred. During the petitioning process, ConAgra was required to submit the following for PAM®: a description of the product, a sample product label, a description of the form in which PAM® would be marketed and the intended dietary uses. 21 C.F.R. 101.12(h). These communications will show that the "nonstick cooking spray (e.g., PAM®)" product category was created for products that are described as lubricants, function as lubricants and are labeled as lubricants – products for which a serving size of 0.25g makes sense. It was not intended for buttery toppings like Parkay Spray®.

Communications with the FDA reflecting PAM's® product characteristics, dietary uses and customary consumption amounts will also help to define the "spray types" category. This is true even if serving size regulations are not expressly referenced because the "spray types" category is premised upon these attributes. Consider an email reflecting the FDA's belief that PAM® and other nonstick cooking sprays function as lubricants for cookware. This is unquestionably relevant to what it means to be a "cooking spray."

ConAgra argues that its communications with the FDA are irrelevant because they come outside of the class period. But that misses the point. This discovery is relevant to the Parkay Spray® label *as used* during the class period. It argues that communications with the FDA about PAM® are irrelevant because the PAM® label is not at issue. This completely ignores the regulatory framework, which reveals that the "spray types" category was created for PAM®. ConAgra's arguments are insufficient to sustain *its* burden. Fact is, the few regulatory communications that exist likely occurred in the months just before formation of the "spray types" category and were reconsidered just before Parkay Spray® was introduced to market. They do not span 15+ years as ConAgra suggests.

Respectfully submitted

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